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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,142	09/15/2003	Stephen Robert Bysouth	C05202-11216US01	8756
181 7590 03/07/2007 MILES & STOCKBRIDGE PC 1751 PINNACLE DRIVE SUITE 500 MCLEAN, VA 22102-3833			EXAMINER GORDON, BRIAN R	
			ART UNIT 1743	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/662,142

Applicant(s)

BYSOUTH ET AL.

Examiner

Brian R. Gordon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9-15-03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 11-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

EXAMINER'S AMENDMENT

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-10, drawn to a modular robotic system, classified in class 422, subclass 63.
 - II. Claims 11-18, drawn to a method of preparing and characterizing formulations in a high throughput mode, classified in class 436, subclass 47.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus is not limited to only performing the process steps of Group II.
3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required

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because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Gianna Arnold on December 18, 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-10. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Specification

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Drawings

9. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the waste station must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Interpretations

10. Applicant claims contain a number of narrative phrases. For example, in reference to claim 1, a number of "for" clauses are employed to describe the intended

use of the elements. In these phrases, additional structures are referenced, but those structures are not positively claimed as elements of the invention. For example, while the rack and vial storage system is said to be for storing racks and vials, the racks and vials are not considered elements of the system. If applicant intends for the racks and vials to be included, it suggested the claim be amended to read: a rack and vial storage system storing therein a plurality of racks and vials. The same applies to the storing materials, ingredients, water, and additives (none of these are considered elements of the invention). Furthermore while it is stated the robotic arm is intended to be employed for the purpose of transferring vials from a first location to a second location, the first and second locations are not positively claimed as elements of the modular robotic system. The claim as drafted does not exclude the first and second locations from being locations within separate apparatuses outside that of the modular system. If it is applicant intent for the first and second locations to be elements within the robotic system, it suggested applicant amend the claim such that the second element after "comprising" reads: "a first and a second location for receiving/holding/storing said racks and vials;" and further amending references thereafter to such elements accordingly. Furthermore as to the subsequent "wherein" clauses directed to the respective locations, it is unclear if it's applicant intent for the elements listed there in to be same as those elements previously claimed above in the claim. If so, it appears as if each clause should read wherein said first/second location is said: Each wherein a clause references a "mixing or homogenizing station". It is unclear if this element is intended to be considered the same or a different element to the previously claimed

"mixing station". If in fact the elements are the same element, consistent terminology referencing such element should be employed within the claims.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 5 are unclear as explained above.

As to the independent claims, it appears as if the respective locations have to be different elements as such, it is suggest applicant further insert a wherein clause stating the respective elements of the locations are different.

Claim 2 refers to "a flexible robotic arm" and "robotic arm" it is unclear if the two elements are same. However, it appears that the elements are different. However as presently drafted it is unclear if "robotic arm" is the same as the robotic arm of claim 1. If so the term "the" or "said" should be inserted in front of the term. Either term should also be inserted before the word "modular" in the last line of the claim. Amending the claims to recite a first robotic arm and a second flexible robotic arm would further aid in the clarification of the claims. The third location is not positively claimed as an element within the system.

As to claim 3, the term "the" or "said" should be inserted in front of the term robotic arm in the next to last line. It should be further noted that while applicant claims

states the use of the comminution stations is for grinding specified solid particles. The specified particles are not considered further limiting of the structure. It is only required that the prior art disclose the ability to grind solids.

As to claims 4 and 6, the wherein clauses directed to "said rack" and "said materials" are not considered further limiting for as stated above the racks and materials are not positively claimed as elements of the invention. Furthermore it is unclear what rack the claim is referencing for the claim states "said rack" as if a single rack had been previously referenced. It appears as if the term "fit" in claims 4, 6, 8, and 9 should be "fitted".

As to claim 5, the respective locations should be positively claimed. It is unclear if there is a difference between "a flexible robotic arm station" and "said flexible robotic arm". If the elements are the same, consistent terminology should be employed. It appears as if the claim should read: "a flexible robotic arm station including a flexible robotic arm that transfers..."

As to the liquids, suspensions, gels, or meltable station, the claim states what material is intended to be dispensed by the station however the cited materials are not claimed as being present therein. It is only required that the prior disclose structure capable of dispensing such material. The term "high viscosity" is relative to the standard of comparison. In the instant case no standard has been provided as to determine what applicant considers as "high".

It appears as if the claim 7 is more so directed to process steps rather than structure. It appears as if the claim should read: "wherein each said rack includes an

identifying bar-code that is read by said robotic arm. Which arm is being referenced in the claim, first or second?

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

14. Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Matsubara et al. US 2006/0615562.

Matsubara et al. disclose a sampling and analysis apparatus (see paragraphs 0074-0078).

[0074] When analysis operation is started, the transportation mechanism 120 (robotic arm) grips a disposable unused reaction container 105 (vial) placed in the part supply area 135 (storage area -first location) by the gripper 128 to transport it to the reaction disk 103 (second location), and releases gripping at a position 121 to put the reaction container on the reaction disk. Then, the transportation mechanism 120 grips the unused nozzle tip 125 placed in the part supply area 135 by the gripper 128 and releases gripping at a coupling position 107 to put the nozzle tip on the coupling position.

[0075] The sample rack 2 transported from the rack supply unit 10 (rack and vial storage) through rack transportation line 60 is transferred to the bypass line 61 of the analysis unit 100 (phase analysis station), and moved to a sample sampling position 111. The pipetting device 102 (pipetting station) positions the movable arm 106 to the coupling position 107, and moves down the coupling tube 104 to engage the unused nozzle tip 125 with the

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end of the coupling tube 104 (refer to FIG. 3). Then, the pipetting device 102 rotates the coupling tube 104 to the sampling position, and inserts the end of the nozzle tip 125 up to slightly lower than the liquid surface of the sample in the sample bottle 5 on the sample rack to suck a preset amount of the sample in the nozzle tip 125 and hold it there.

[0076] Since the unused reaction container 102 has been moved from the position 121 to a discharging position 112 (mixing station), the pipetting device 102 discharges the preset amount of the sample held in the nozzle tip 125 to the reaction container 105 placed at the discharging position 112. After the sampling is repeated necessary times relating to the one sample, the pipetting device 102 moves the coupling tube 104 to a detaching position 108 to remove the used nozzle tip 125 from the coupling tube 104. The removing operation of the nozzle tip is performed by bringing the upper end surface of the nozzle tip in contact with a lower surface of a split groove larger than an outer diameter of the coupling tube 104 and smaller than an outer diameter of the upper end of the nozzle tip 125, and then moving the coupling tube 104 upward. The removed nozzle tip is collected in a disposal box. In a case where there are a plurality of analysis items to be analyzed by the analysis unit 100 on a sample in a single sample bottle, one nozzle tip is continuously used for sampling the samples of these analysis items. After that, the nozzle tip is removed from the coupling tube 104. By doing so, number of consumed nozzle tips can be reduced.

[0077] The reaction container receiving the sample is moved to a reagent receiving position 113 (mixing station) by the reaction disk 103. The reagent pipetter 110 sucks a dispersed solution of fine magnetic particles as a solid phase into the pipette nozzle at a position 118, and discharges the dispersed solution to the reaction container on the reagent receiving position 113. Thus, a first immune reaction of binding a substance to be analyzed in the sample, for example, an antigen to the solid phase is started. After a predetermined time, a reagent containing a label substance sucked into the pipette nozzle is discharged from the reagent pipetter 110 at the position 119 into the reaction container again positioned at the reagent receiving position 113. Thus, a second immune reaction of binding the label substance to the substance to be analyzed in the reaction container is started. The pipette nozzle of the reagent pipetter 110 is used by washing every reagent pipetting.

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[0078] After that, the reaction container 105 containing the reaction solution of the immune reaction is positioned at a sucking position 114 by the reaction disk 103. The sipper mechanism 130 introduces the reaction solution to a detection unit 140 (phase stability station) from the reaction container at the sucking position 114 through a sucking nozzle. In the detection unit 140, the liquid phase containing substance not binding with the magnetic particles flows through while the magnetic particles are being attached onto the wall surface by a magnet. By doing so, the solid is separated from the liquid phase. The separated liquid phase is conducted to a measuring unit to measure fluorescence or chemi-luminescence of the label substance contained in the liquid phase. Otherwise, the separating position and the measuring unit are commonly used, and measurement is performed by generating chemi-luminescence or electro-chemical-luminescence from the label substance binding with the magnetic particles through the substance to be analyzed. After that, the sipper mechanism 130 sucks a washing solution from a washing tank 131 through the sucking nozzle to wash the flow passage of the detection unit 140. The used reaction container is removed from the reaction disk 103 by the transportation mechanism at the position 121.

As to claim 4,

[0053] The sample rack 2 is, for example, a rectangular parallelepiped shaped holder, and can hold the plurality of sample bottles 5 (Refer FIG. 2) in a row along the lateral direction of the sample rack. To the sample rack 2 of this type, a bar-code label having coded rack identification information including kind of rack and rack number is attached. In each of the sample bottle 5, a bar-code label having coded sample information such as bottle identification number, patient code, medical section number, sample receipt number is attached

The device includes a pipetting device that is fitted with disposable nozzles and a second nozzle is washed by fluid that may be expelled to waste.

Allowable Subject Matter

15. Claims 2-3 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. Claims 5-10 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

17. The following is a statement of reasons for the indication of allowable subject matter: The prior art of record does not disclose a system including a third location and a second flexible robotic arm, wherein said flexible robotic arm is operable to transfer racks from said first robotic arm to said third location.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Komiyama; Yasuaki et al.; Shu; Frank R. et al.; McGrath; Andrew et al.; Itoh; Teruaki; Lenz; Steven J.; Pressman, Norman J. et al.; Qureshi, Humayun et al.; Fermier; Adam M. et al.; Safar, Scott et al.; Itoh; Teruaki; Rackers; Kevin J.; Gebrian; Peter Louis et al.; Dales; G. Cameron et al.; Tamura; Tomoaki et al.; Carey, Glen et al.; Copeland; Anne B. et al.; Yaremko; Mykola et al.; Gordon, Steven J. et al.; Torchia; Mark G. et al.; Roginski; Edward T.; Tajima; Hideji; Dales, G. Cameron et al.; Coassin; Peter J. et al.; Rao; Prabhakar P. et al.; and Kurosaki; Tsuyoshi et al. disclose devices including robotic arms.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



brg

BRIAN R. GORDON
PRIMARY EXAMINER